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09/271,584	03/18/1999	EDUARDO BLUMWALD	4001	4345

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/271,584

Applicant(s)

BLUMWALD ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7,8,10-12,14-16,18,19,21-33,48,49,53,54 and 56 is/are pending in the application.
- 4a) Of the above claim(s) 15,16,33,48 and 49 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 56 is/are allowed.
- 6) ☒ Claim(s) 1,5,7,8,10-12,14,18,19,21-32,53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21,22,39.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. The claims have been amended as requested in Paper No. 36, filed 18 March 2003, and the substitute specification has been entered. Claims 1, 5, 7-8, 10-12, 14-16, 18-19, 21-33, 48-49, 53-54 and 56 are pending.
2. This application contains claims 15-16, 33 and 48-49 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. Claims 33 and 48-49 are withdrawn from consideration. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32, 53-54 and 56 are examined.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

5. The objection to claims 5, 8, 12 and 17 under 37 CFR 1.75(c) as being in improper form is withdrawn in light of amendment to the claims.
6. The objection to claims 5, 8, 12 and 17 because of informalities is withdrawn in light of amendment to the claims.
7. The rejection of claims 1-14, 17-32 and 53-56 under 35 U.S.C. 112, first paragraph, for new matter is withdrawn in light of amendment to the claims.
8. The rejections of claims 1-3, 5-6 and 9-14 under 35 U.S.C. 102(b) as being clearly anticipated by Brant et al (1997, GenBank Accession No. T51330), claims 1-3, 5-6 and 9-14 under 35 U.S.C. 102(b) as being clearly anticipated by Sumitomo Sieyaku KK (1993, GenBank

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Accession No. Q51524), and claims 1-3, 5-6, 8-14, 17-20, 26 and 31 under 35 U.S.C. 102(b) as being anticipated by Hahnenberger et al (1996, Proc. Natl. Acad. Sci., USA 93:5031-5036) are withdrawn light of amendment to the claims.

Claim Rejections - 35 USC § 112

9. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32 and 53-54 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids that encode SEQ ID NO:2, methods of using the nucleic acids to produce plants, and plants thereby obtained, does not reasonably provide enablement for Na⁺/H⁺ transporter-encoding nucleic acids that hybridize to SEQ ID NO:1 under “moderately stringent” or “highly stringent” conditions, methods of using the nucleic acids to produce plants, and plants thereby obtained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 19 November 2002, as applied to claims 1-14, 17-32 and 53-54. Applicant’s arguments filed 18 March 2003 have been fully considered but they are not persuasive.

Applicant urges that Table 4 (pg 60) provides specific conditions for highly stringent conditions and that Example 9 of the Written Description Guidelines states that one of skill in the art would not expect substantial variation among species encompassed within the scope of the claim because highly stringent conditions yield structurally similar DNAs. Applicant urges that thus, the claims are not drawn to a broad range of nucleic acids (response pg 11-12).

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This is not found persuasive. Table 4 does not provide exact hybridization conditions, but includes ranges of hybridization and wash temperatures. Table 4 also does not specify hybridization and wash times, which are necessary because different nucleic acids will hybridize under different hybridization and wash times. Furthermore, pg 29 of the specification states "Preferable hybridization conditions are about those in Table 4" (lines 16-17). Thus, Table 4 represents possible conditions, but not definitive ones. Applicant's arguments with respect to Example 9 of the Written Description Guidelines have no relevance to an enablement rejection, as enablement and written description are not the same.

Applicant urges that with respect to plant nucleic acids that hybridize under moderately stringent conditions, the specification provides those conditions in Table 4, and testing hybridization conditions is routine in the art. Applicant urges that the nucleic acids covered will be relatively limited, so the breadth of the claims is reasonably narrow. Applicant urges that the limitation that the nucleic acids encode a Na^+/H^+ transporter narrows the breadth of the claims (response pg 12).

This is not found persuasive because the specification must teach what is claimed, no matter how narrow or how broad. The instant specification does not teach the sequence of a PNHX-encoding nucleic acid that hybridizes to SEQ ID NO:1 under "moderately stringent" or "highly stringent" conditions. The specification also does not teach any other Arabidopsis nucleic acids that encode Na^+/H^+ transporters.

Applicant urges that the skill in the art is high and performed at the graduate or post-doctoral level. Applicant further urges that transformation of plants is well-developed and that expressing a gene in a plant is fairly predictable. Applicant also urges that the specification

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teaches how to test for Na^+/H^+ transporter activity. Applicant urges that the specification teaches that overexpression of Na^+/H^+ transporters in plants provides salt tolerance. Applicant urges that a single example of plant transformation is sufficient to enable the claim (response pg 13).

This is not found persuasive because the rejection is not that plants transformed with SEQ ID NO:1 would not be salt tolerant but that the specification is not enabled for nucleic acids that hybridize to SEQ ID NO:1 and that encode Na^+/H^+ transporters. Thus, the specification is not enabled for plants transformed with those nucleic acids.

10. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32 and 53-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 19 November 2002, as applied to claims 1-14, 17-32 and 53-54, due to amendment. Applicant's arguments filed 18 March 2003 have been fully considered but they are not persuasive.

In addition to the rejection as presented in the prior Office action, claims 1 and 18, part (c), and claim 53, part (iii), do not recite a function for any protein encoded by the nucleic acid, nor do they require that it does encode a protein. Written description is thus lacking for the nucleic acid.

Applicant urges that Example 9 of the Written Description Guidelines covers hybridization claims, stating that the art indicates that hybridization techniques using known DNA as a probe under highly stringent conditions were conventional at the time of filing.

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Applicant urges that the instant claims are drawn to a genus of nucleic acids that must hybridize to SEQ ID NO:1 and that must encode a protein with a specific activity. Applicant urges that the example states that one of skill in the art would not expect substantial variation among species encompassed within the scope of the claim because highly stringent conditions yield structurally similar DNAs (response pg 10-11).

This is not found persuasive because the specification does not describe the structural features, *i.e.*, the sequence, of such nucleic acids. The Written Description Guidelines are just guidelines; in the instant case, because “highly stringent” and “moderately stringent” are not defined, and because they have not set meaning in the art, they cannot be used to define the claimed nucleic acid.

Applicant urges that the specification indicates that the inventor had possession of plant nucleic acids that hybridize under moderately stringent conditions; although less structurally related DNAs are included, the claims are limited to plant DNAs, limiting the scope of the claimed material. Applicant urges that one of skill in the art would realize that DNAs that hybridize to SEQ ID NO:1 under moderately stringent conditions would encode Na⁺/H⁺ transporters. Applicant urges that it would be routine for one of skill in the art to confirm the activity of the protein (response pg 11).

This is not found persuasive because the specification must describe what is claimed, no matter how narrow or how broad. The instant specification does not describe the sequence of a PNHX-encoding nucleic acid that hybridizes to SEQ ID NO:1 under “moderately stringent” or “highly stringent” conditions.

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11. Claims 1, 5, 7-8, 10-12, 14, 18-19, 21-32 and 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 19 November 2002, as applied to claims 1-14, 17-32 and 53-56. Applicant's arguments filed 18 March 2003 have been fully considered but they are not persuasive.

Claim 1, part (c), claim 18, part (c), and claim 53, part (a), are indefinite in their recitation of "highly stringent conditions" and claim 1, part (d), claim 18, part (d), and claim 53, part (a), are indefinite in their recitation of "moderately stringent conditions".

Applicant urges that the claims need not recite times for hybridization and wash steps because hybridization is a routine procedure familiar to one of skill in the art, who would understand how long each step should last. Applicant urges that an example of hybridization is provided on pg 57 and that the specification references "Molecular Cloning" (response pg 14).

This is not found persuasive because the definitions of highly stringent and moderately stringent conditions vary according to who is doing the experiment and the GC content of the nucleic acid they desire to isolate. This can even be seen in Table 4 of the specification, which recites temperature ranges rather than exact temperatures. Different hybridizations conditions will detect different nucleic acids. Thus, knowing what nucleic acids are included in and excluded from the claim requires knowing the exact hybridization conditions, including salt concentration, temperature and time.

Claims 31-32 are indefinite because they lack agreement between the preamble of the methods and the positive method steps. Applicant urges that that the claims produce the result of

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the preamble and that following the claimed steps will produce what is claimed in the preamble (response pg 14-15). This is not found persuasive because due to position effects, etc., not all plants transformed with a nucleic acid will express the nucleic acid.

The following rejections are new, due to amendment:

Claims 1 and 18, part (b), are indefinite in their recitation of “the same amino acid sequence as encoded by the nucleic acid sequence of (a)” and claim 53, part (a), is indefinite in its recitation of “the same amino acid sequence as encoded by the nucleic acid sequence of (i)”. A nucleic acid has 6 reading frames, and each reading frame has at least one open reading frame; many of the reading frames will have multiple open reading frames. It is thus entirely unclear to which amino acid sequence the claims refer.

Claim 1, parts (c) and (d), claim 18, parts (c) and (d), and claim 53, part (a), are indefinite in their recitation of “specifically hybridizes”. It is unclear what kind of hybridization is considered specific, and thus it is unclear what nucleic acids are included in the claim. Any that hybridize under the recited “conditions”? Does specific hybridization mean the claimed nucleic acid hybridizes and no other does? - this definition would result in a circular definition for the claimed nucleic acid.

Claims 5 and 12 are indefinite in their recitation of “the transgenic plant of claim 1, wherein the PNHX transporter polypeptide”. The plant of claim 1 has any of a number of nucleic acids; only the ones in part (d) encode a PNHX transporter polypeptide. However, the wording of claims 5 and 12 does not state that the transgenic plant comprises the nucleic acid of part (d) and the PNHX transporter polypeptide has the recited properties. The claim further only defines part (d). It is not clear if this is what Applicant intended.

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Claim 53 lacks antecedent basis for the limitation "said nucleic acid" in part (a), line 9.

Claim Rejections - 35 USC § 102

12. Claims 1, 5, 8, 10, 12, 14, 18-19, 21-24, 26-28, 30-32 and 53-54 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Young et al (WO 91/06651). The rejection is repeated for the reasons of record as set forth in the Office action mailed 19 November 2002, as applied to claims 1-3, 5-6, 8-14, 17-24, 26-28, 30-32 and 53-54. Applicant's arguments filed 18 March 2003 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art would not expect the *sod2* nucleic acid to hybridize to SEQ ID NO:1 under the conditions defined in Table 4 and that *sod2* is a yeast Na⁺/H⁺ transporter, not a plant transporter (response pg 16).

This is not found persuasive because as discussed above, Table 4 does not defined moderately or highly stringent conditions. Furthermore, the statement that the *sod2* nucleic acid would not to hybridize to SEQ ID NO:1 is an assertion only. Additionally, under some definitions, yeast is considered a plant.

Claim Rejections - 35 USC § 103

13. Claims 1, 5, 8, 10, 12, 14, 18-19, 21-28, 30-32 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (WO 91/06651) in view of Gordon-Kamm et al (1990, Plant Cell 2:603-618). The rejection is repeated for the reasons of record as set forth in the Office action mailed 19 November 2002, as applied to claims 1-3, 5-6, 8-14, 17-28, 30-32

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and 53-54. Applicant's arguments filed 18 March 2003 have been fully considered but they are not persuasive.

Applicant urges that one of skill in the art would not expect the *sod2* nucleic acid to hybridize to SEQ ID NO:1 under the conditions defined in Table 4 and that *sod2* is a yeast Na^+/H^+ transporter, not a plant transporter (response pg 16-17).

This is not found persuasive for the reasons discussed above.

Applicant urges that none of the references teach or suggest all of the claim limitations, and any *prima facie* case is rebutted by the unexpected results that the plants are salt tolerant. Applicant urges that Young et al teach away from this because Figures 3A and 3B teach that the wild-type *sod2* gene does not provide salt tolerance while the mutant *sod2* gene does. Applicant thus urges that one of ordinary skill in the art would not expect the wild-type PNHX gene to provide salt tolerance to a plant (response pg 17-18).

This is not found persuasive. Figure 3A shows the salt tolerance of untransformed, wild-type yeast, while Figure 3B shows the salt tolerance of mutant yeast. Young et al teach that plants transformed with *sod2* are sodium and lithium tolerant (pg 28, paragraph 3, to pg 35); thus, Applicant's results are not unexpected.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (*i.e.*, a wild-type gene) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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Furthermore, Young et al suggest transformation of monocots with *sod2* (pg 9, paragraph

1). Thus, all the claim limitations are taught or suggested.

14. Claim 56 is free of the prior art, given the failure of the prior art to teach or suggest the isolated nucleic acid of SEQ ID NO:1.

15. Claim 56 is allowed, for the reasons stated above.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
May 14, 2003



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